REMARKS

I. The Office Action

The Office maintained the rejection of claims 23 and 25 under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite. Claims 17-19, 24, and 25 remain rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Sawada et al., *J. Exp. Med.*, *187*(9), 1439-1449 (1998) ("the Sawada reference"). Claims 17-25 remain rejected under 35 U.S.C. § 103(a) as assertedly being obvious in view of Sawada taken with Lapidot et al., *Leukemia*, *16*(1), 1992-2003 (2002) ("the Lapidot reference"). Reconsideration of these rejections is respectfully requested.

II. Pending Claims and Claim Amendments

Claim 16 has been amended to correct a typographical error. Claim 17 has been amended to characterize the isolated population as comprising human cord blood or bone marrow stem cells. Claims 23 and 25 have been amended to remove the term "about." Claims 41-47 are new, are directed to the elected invention, and are supported by the specification at, e.g., page 6, lines 7-10 and 15-16; page 12, line 31, through page 13, line 16; page 34, line 16, through page 38, line 2; and original claims 23 and 25. No new matter has been added by way of the amendments or new claims. Claims 1-47 are pending, and claims 17-25 and 41-47 are currently under examination.

III. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Is Moot.

The Office rejected claims 23 and 25 for reciting "at least about" 3% of the population or 1 microgram/ml, respectively, which assertedly renders the claims indefinite. Applicants respectfully disagree with the rejection and maintain that the Office has misapplied the case law cited in the Office Action. However, solely in an effort to advance prosecution of the application, claims 23 and 25 have been amended to remove the term "about," rendering the rejection moot.

IV. The Rejections Under 35 U.S.C. § 102(b) Should Be Withdrawn.

The Office rejected claims 17-19, 24, and 25 under Section 102(b) as assertedly being anticipated by Sawada. The rejection is respectfully traversed for the reasons set forth below.

The Office maintains that the Sawada reference discloses isolated peripheral blood from transgenic mice comprising a CXCR4 coding region, and that peripheral blood "is known in the art to have some hematopoietic stem cells." (Office Action, page 5.) Thus, according to the Office, the reference discloses an isolated population of stem cells having a transgene encoding CXCR4 as recited in claim 17. With respect to claims 19, 24, and 25, the examiner contends that the Sawada reference indicates that immature myeloid and erythroid lineage cells are produced in the disclosed transgenic mice, and the recitation of low and high concentrations of SDF-1 does not further limit the structure of the stem cell population.

A reference anticipates the pending claims *only* if the reference teaches *each and every element* of the pending claims. See, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Sawada fails to disclose each and every feature of the amended claims. Claim 17 has been amended to recite an isolated population of *human cord blood or bone marrow* stem cells. The Sawada reference does not teach obtaining human stem cells, nor does the reference disclose collecting cord blood or bone marrow from the transgenic mice described therein. As acknowledged by the Office, the *in vitro* experiment described in Sawada utilized peripheral blood to identify mechanisms of HIV infection of lymphocytes (see, e.g., page 1440, paragraph bridging columns 1 and 2; and page 1441, column 2, first full paragraph). Thus, the reference does not disclose each element of claim 17 (or claims dependent thereon) as required to sustain a rejection under 35 U.S.C. § 102(b).

Sawada also fails to anticipate the subject matter of new claims 43 and 44 (and claims dependent hereon). The new claims are directed to an isolated population of peripheral blood stem cells and incorporate the features of existing claim 22 and 23, which were not rejected by the examiner for allegedly being anticipated by the Sawada reference. Indeed, the Sawada reference does not teach or suggest an isolated population of stem cells

comprising about 1-5% or at least 3% $CD34^{+}/CD38^{-/low}$ hematopoietic stem cells. Thus, the new claims are novel in view of the Sawada reference.

For the reasons set forth above, the subject matter of the pending claims is novel over the Sawada reference, and the rejection under Section 102 should be withdrawn.

V. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn.

The Office rejected claims 17-25 under Section 103(a) as assertedly being unpatentable over Sawada taken with Lapidot. The rejection is respectfully traversed; the cited references do not render obvious the subject matter of the amended claims.

The Office asserts that the Sawada reference discloses isolated peripheral blood from transgenic mice comprising a CXCR4 transgene, which the Office interprets to be "an isolated population [of] stem cells comprising a transgene encoding CXCR4." The Lapidot reference is cited as supplementing the disclosure of Sawada with respect to the subject matter of claims 21-23. In this regard, the examiner acknowledges that the Sawada reference does not disclose a cell population comprising $CD34^{+}/CD38^{-/low}$ progenitor cells, but asserts that one of ordinary skill would deduce that the peripheral blood of Sawada contains $CD34^{+}/CD38^{-/low}$ progenitor cells in view of Lapidot. The examiner characterizes the Lapidot reference as teaching that "mammals have a population of immature primitive progenitor cells in cord blood and peripheral blood which are $CD34^{+}/CD38^{-/low}$ stem cells which are about 1-5% of the population" and asserts that "there is a strong suggestion that overexpressing CXCR4 has not altered the percentage of $CD34^{+}/CD38^{-/low}$ cells in the cord blood or peripheral blood population of the transgenic mice." (Office Action, page 12.)

With respect to claim 17 (and claims dependent thereon), the Sawada reference does not teach or suggest isolating a population of *human* stem cells comprising a CXCR4 transgene. The purpose of the study described in Sawada was to determine if chemokine receptors render mouse primary lymphocytes, i.e., mature thymocytes, susceptible to HIV infection (see, e.g., the paragraphs bridging pages 1439-1440, and pages 1443-1444). To this end, the Sawada authors generated transgenic mice expressing CXCR4. The

reference does not suggest generating transgenic *humans* to explore the mechanism of HIV infection, and there is nothing in the reference directing one of ordinary skill in the art to (1) isolate stem cells from a human, and (2) introduce a CXCR4 transgene into human cells. Additionally, Sawada's disclosure of a peripheral blood sample to study HIV infection in T-cells does not suggest isolating stem cells from *cord blood* or *bone marrow*. The Lapidot reference does not cure the deficiencies of the Sawada reference in this regard; Lapidot's general discussion of stem cell subpopulations would not motivate one of ordinary skill to modify the teachings of Sawada for determining HIV infectivity of primary lymphocytes.

The subject matter of new claims 43-47 also is not rendered obvious by the Sawada and Lapidot references. The claimed isolated population of peripheral blood stem cells comprising a transgene encoding CXCR4 comprises about 1-5% or least 3% $CD34^+/CD38^{-/low}$ hematopoietic stem cells. The references, alone or in combination, do not teach or suggest such a stem cell population. As explained above, the Sawada reference does not teach or suggest isolating a population of human stem cells, and Lapidot does not cure this deficiency in the Sawada disclosure. Furthermore, the examiner's characterization of the teachings of the Lapidot reference is not supported by the publication's disclosure; the reference does not teach or suggest a population of peripheral blood stem cells having the claimed percentages of $CD34^+/CD38^{-/low}$ cells. The Lapidot reference discloses that $CD34^+/CD38^-$ represent up to 5% of all *cord blood* $CD34^+$ cells (page 1994, column 2). The reference does not teach or suggest that *peripheral blood* comprises a population of immature primitive progenitor having about 1-5% $CD34^+/CD38^{-/low}$ stem cells. The data provided in the specification demonstrate that the percentage of $CD34^+/CD38^{-/low}$ stem cells in a population of peripheral blood $CD34^+$ cells is *less than 1%*. Example 2 of the specification describes populations of mobilized peripheral blood $CD34^+$ cells transfected with an expression construct comprising a CXCR4 transgene or an expression construct lacking the CXCR4 transgene. The population of peripheral blood $CD34^+$ stem cells lacking the transgene consisted of only 0.5% $CD34^+/CD38^{-/low}$ stem cells (specification at page 37, lines 29-31). Thus, the Lapidot reference's disclosure pertaining to cord blood cells does not translate to the $CD34^+/CD38^{-/low}$ stem cell content of peripheral blood stem cell populations. Furthermore, contrary to the examiner's assertions, Applicants demonstrated that overexpressing CXCR4 does, in fact, alter the percentage of $CD34^+/CD38^{-/low}$ cells in

peripheral blood $CD34^+$ stem cell populations. Example 2 reports that CXCR4 transduced stem cells from mobilized peripheral blood demonstrated a higher percentage of $CD34^+/CD38^{-/low}$ stem cells, 2.9%, compared to peripheral blood $CD34^+$ stem cells lacking the CXCR4 transgene, 0.5% (see, e.g., page 37, line 17, through page 38, line 2, and Figure 3C). Thus, the cited references do not teach or suggest the isolated population of peripheral blood stem cells of new claims 43-47.

Sawada and Lapidot, alone and in combination, fail to render obvious the claimed isolated population of stem cells. Accordingly, the Section 103 rejection should be withdrawn.

VI. Conclusion

In view of the above amendments and remarks, Applicants believe that the pending application is in condition for allowance. The Office is invited to contact the undersigned attorney by telephone if there are issues or questions that might be efficiently resolved in that manner.

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Respectfully submitted,

By _____

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